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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/784,528	02/23/2004	Arthur M. Brown	22884/04085	1521
24024	7590	09/25/2006	EXAMINER	
CALFEE HALTER & GRISWOLD, LLP 800 SUPERIOR AVENUE SUITE 1400 CLEVELAND, OH 44114			DAVIS, MINH TAM B	
			ART UNIT	PAPER NUMBER
			1642	

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/784,528

Applicant(s)

BROWN ET AL.

Examiner

MINH-TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 19 January 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-23 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☐ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

Claims 1, 11 are linking claims linking groups I-XII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1, 11. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP, 804.01.

Group I. Claims 1-2, 4-5, 7-9, 11-13, 16, 19, drawn to a method for inducing apoptosis or treating cancer, which is an epithelial carcinoma, using human KChAP protein, or variant thereof, classified in class 514, subclass 2.

Group II. Claims 1-2, 4-5, 7-9, 11-13, 16, 19, drawn to a method for inducing apoptosis or treating cancer, which is a lymphoma, using human KChAP protein, or variant thereof, classified in class 514, subclass 2.

Group III. Claims 1-2, 4-5, 7-9, 11-13, 16, 19, drawn to a method for inducing apoptosis or treating cancer, which is a leukemia, using human KChAP protein, or variant thereof, classified in class 514, subclass 2.

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Group IV. Claims 1-2, 4-5, 7-9, 11-12, 14, 16, 19, drawn to a method for inducing apoptosis or treating cancer, which is prostate cancer, using human KChAP protein, or variant thereof, classified in class 514, subclass 2.

Group V. Claims 1, 3, 6, 10-13, 15, 17-18, drawn to a method for inducing apoptosis or treating cancer, which is an epithelial carcinoma, using a nucleic acid encoding a human KChAP protein, or variant thereof, classified in class 514, subclass 44.

Group VI. Claims 1, 3, 6, 10-13, 15, 17-18, drawn to a method for inducing apoptosis or treating cancer, which is a lymphoma, using a nucleic acid encoding a human KChAP protein, or variant thereof, classified in class 514, subclass 44.

Group VII. Claims 1, 3, 6, 10-13, 15, 17-18, drawn to a method for inducing apoptosis or treating cancer, which is a leukemia, using a nucleic acid encoding a human KChAP protein, or variant thereof, classified in class 514, subclass 44.

Group VIII. Claims 1, 3, 6, 10-12, 14-15, 17-18, drawn to a method for inducing apoptosis or treating cancer, which is prostate cancer, using a nucleic acid encoding a human KChAP protein, or variant thereof, classified in class 514, subclass 44.

Group IX. Claims 11-13, 15-19, drawn to a method for inducing apoptosis or treating cancer, which is an epithelial carcinoma, using a human KChAP protein, or variant thereof, **and** the encoding nucleic acid, classified in class 514, subclasses 2 and 44.

Group X. Claims 11-13, 15-19, drawn to a method for inducing apoptosis or treating cancer, which is a lymphoma, using a human KChAP protein, or variant thereof, **and** the encoding nucleic acid, classified in class 514, subclasses 2 and 44.

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Group XI. Claims 11-13, 15-19, drawn to a method for inducing apoptosis or treating cancer, which is a leukemia, using a human KChAP protein, or variant thereof, **and** the encoding nucleic acid, classified in class 514, subclasses 2 and 44.

Group XII. Claims 11-12, 14-19, drawn to a method for inducing apoptosis or treating cancer, which is prostate cancer, using a human KChAP protein, or variant thereof, **and** the encoding nucleic acid, classified in class 514, subclasses 2 and 44.

Claim 20 is a linking claim, linking groups XIII-XX. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 20. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP, 804.01.

Group XIII. Claims 20-21, drawn to a method for detecting liver cancer, using an antibody to KChAP protein, classified in class 435, subclass 7.1.

Group XIV. Claims 20-21, drawn to a method for detecting brain cancer, using an antibody to KChAP protein, classified in class 435, subclass 7.1.

Group XV. Claims 20-21, drawn to a method for detecting colon cancer, using an antibody to KChAP protein, classified in class 435, subclass 7.1.

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Group XVI. Claims 20-21, drawn to a method for detecting rectal cancer, using an antibody to KChAP protein, classified in class 435, subclass 7.1.

Group XVII. Claims 20, 22, drawn to a method for detecting liver cancer, using KChAP mRNA, classified in class 435, subclass 6.

Group XVIII. Claims 20, 22, drawn to a method for detecting brain cancer, using KChAP mRNA, classified in class 435, subclass 6.

Group XIX. Claims 20, 22, drawn to a method for detecting colon cancer, using KChAP mRNA, classified in class 435, subclass 6.

Group XX. Claims 20, 22, drawn to a method for detecting rectal cancer, using KChAP mRNA, classified in class 435, subclass 6.

Group XXI. Claim 23, drawn to a method for inhibiting cell cycling in cancer cells, using a nucleic acid encoding human KChAP protein, classified in class 514, subclass 44.

The inventions are distinct, each from the other because of the following reasons.

Inventions I-XXI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). The method of diagnosing cancer using an antibody, the method of diagnosing cancer using a polynucleotide, and the method of treating cancer, or inhibiting cell cycle, using a polypeptide or a polynucleotide are all unrelated as they comprise distinct steps and utilize different products which demonstrates that each method has a different mode of operation. Each invention performs its function using a structurally and functionally divergent material. Moreover, the methodology and materials necessary for diagnosis of cancer differ significantly for each of the materials. For diagnosis

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using the polynucleotide, hybridization may be used. For diagnosis using the antibody, quantitation of labeled antibody may be used. For treatment of cancer or inhibiting cell cycle, using the polypeptide, or the polynucleotide, the polypeptide or the polynucleotide is administered to a patient, using any mode of administration. In addition, each type of cancer to be treated or diagnosed is different, having different etiology and characteristic, and does not predictably have the same response to the same drug. Therefore, each method is divergent in materials and steps. For these reasons the Inventions I-XXI are patentably distinct.

Furthermore, the distinct steps and products require separate and distinct searches. There may be journal articles devoted solely to detecting the presence of a polypeptide, or a polynucleotide in a cancer, which would not have described methods of treating the cancer, using the polypeptide or polynucleotide, or a method for inhibiting cell cycling, or vice versa. Similarly, there may be journal articles devoted solely to treating a cancer, using a polypeptide, which would not have described methods of treating another cancer using said polypeptide, or methods of treating said cancer or another cancer, using a polynucleotide. As such, it would be burdensome to search the inventions of Groups I-XXI together.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, JEFFREY SIEW can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS  
September 14, 2006

  
JEFFREY SIEW  
SUPERVISORY PATENT EXAMINER